

## REMARKS

In the Office Action, the Specification is objected to; claims 1-10 and 12-20 are rejected under the judicially created doctrine of obviousness-type double patenting; and claims 1-10 and 12-20 are rejected under 35 U.S.C. § 103. In response, claims 1, 6, 10, 12, 13 and 20 have been amended. Claims 2, 5 and 11 have been canceled without prejudice or disclaimer. Applicants believe that the rejections have been overcome in view of the amendments and at least for the reasons set forth below.

At the outset, the Patent Office has objected to the Abstract. As previously provided, Applicants have amended the specification and thus believe that they have been responsive to the Patent Office's comments (Office Action, pages 2-3). Therefore, Applicants respectfully request that the objection to the Specification be withdrawn.

In the Office Action, claims 1-10 and 12-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6,777,391. At the outset, Claims 2 and 5 have been canceled without prejudice or disclaimer as previously discussed, and thus, the obviousness-type double patenting rejection with respect to same has been rendered moot and further should be withdrawn in view of same.

With respect to the remaining claims at issue, Applicants are submitting herewith a Terminal Disclaimer. Therefore, Applicants believe that this rejection should be withdrawn.

In the Office Action, claims 1-10 and 12-20 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over XP-002158762. At the outset, Claims 2 and 5 have been canceled without prejudice or disclaimer and thus the obviousness rejection with respect to same has been rendered moot and further should be withdrawn in view of same.

Of the remaining pending claims at issue, claims 1, 10, 12, 13 and 20 are the sole independent claims. Claim 1 recites a composition for an infant formula. The composition includes whey protein wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropetide has been removed; casein protein; free arginine; histidine; milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan or a mixture thereof. Claim 10 recites a method of producing an infant formula. The method includes blending whey, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropetide has been removed, and casein protein together with free arginine; free

histidine; and milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan or a mixture thereof and homogenizing the blended mixture.

Claim 12 recites a method of treating malnutrition. The method includes administering a composition that contains whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan or a mixture thereof. Claim 13 recites an infant formula that includes hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan and mixtures thereof. Claim 20 recites a method of providing nutrition to an infant. The method includes administering a composition that includes whey protein wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan or a mixture thereof.

According to the claimed invention, a composition for an infant formula and a method for its preparation and use are provided wherein the composition contains specific compounds which provide a balanced amount of all essential amino acids to an infant. Such compounds particularly include hydrolysed sweet whey protein from which caseino-glyco-macropeptide ("CGMP") has been removed. This provides a composition with a reduced threonine and an increased tryptophan content which leads to a lower content of nitrogen in the compositions.

Applicants believe that the cited art is distinguishable from the claimed invention. The cited art provides a preparation of a nutritive composition which may be used as an infant food, particularly suitable for the treatment of some diseases. The composition includes whey powder, casein, different amino acids, lipids, carbohydrates, minerals and vitamins. See, XP-002158762, Abstract.

At a minimum, nowhere does the cited art disclose or suggest to remove the CGMP from whey protein, let alone sweet whey protein, in contrast to the claimed invention. Since this peptide subunit of the kappa-casein has a high threonine content but no aromatic amino acids, its removal leads to compositions that have a lower threonine content and a comparatively increased content of aromatic amino acids. This ensures that the composition has the required amino acids

in sufficient amounts and also that the threonine content is reduced, where threonine represents the major source of nitrogen and generally yields an undesired overload with nitrogen. Again, the claimed compositions and methods of preparation and use include, in part, sweet whey protein from which caseino-glyco-macropptide has been removed. This provides a reduced threonine and an increased tryptophan content and further can provide a balanced amount of all essential amino acids to an infant.

Applicants further submit that the claimed invention is distinguishable from the cited art because the sweet whey fraction is hydrolysed as fully supported in the specification, for example at, page 5, lines 7-16. Sweet whey protein is hydrolysed, for example, to prevent allergic reactions in infants at risk and to make the protein easier to digest. See, Applicants' specification, for example, p. 5, line 7-8.

In contrast, the cited art generally provides the presence of whey powder, but fails to teach or suggest that the whey is hydrolysed, let alone hydrolysed to prevent allergic reaction in babies and/or infants that would use such, in a formula. The emphasis of the cited art relates to a formula for babies or infants with urea cycle and/or kidney disorder. Indeed, nowhere does the cited art make reference to any type of allergic conditions. See, XP-002158762, Abstract. Again, the hydrolysed sweet whey protein as claimed can prevent allergic reactions in infants at risk of same.

Further, Applicants respectfully submit that claim 6 is distinguishable from the cited art. Claim 6 depends from claim 1 and further includes that the sweet whey protein is treated to remove lactose. If the sweet whey fraction used is substantially lactose free, Applicants found that the protein is subjected to much less lysine blockage during the hydrolysis process. This enables the extent of lysine blockage to be reduced from about 15% by weight of total lysine to less than about 10% by weight of lysine; for example about 7% by weight lysine. This greatly improves the nutritional quality of the protein source. See, Specification, page 5, lines 18-23. Clearly, this contrasts the cited art Abstract where no reference is made to a whey fraction that is substantially lactose free. Therefore, Applicants believe that the cited art is distinguishable from the claimed invention at least for the reasons discussed above.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of the same.

Respectfully submitted,

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